UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 4:24CR10-2 HEA(SPM)**
	)	
MOHD AZFAR MALIK, M.D. (2),	)	
	)	
Defendant.	)	

MEMORANDUM OPINION
AND REPORT AND RECOMMENDATION OF
UNITED STATES MAGISTRATE JUDGE

All pretrial matters were referred to the undersigned United States Magistrate Judge pursuant to 28 U.S.C. § 636(b). This matter is before the Court on Defendant Mohd Azfar Malik, M.D.'s Motion to Dismiss the Drug Trafficking Counts in the indictment (ECF No. 54 & 74), which is opposed by the United States. ECF No. 64.[1]

PROCEDURAL HISTORY AND FACTUAL BACKGROUND

On January 10, 2024, a federal grand jury returned an indictment charging Defendant Mohd Azfar Malik, M.D., and co-defendant Asim Muhammad Ali, M.D., with conspiracy to illegally distribute controlled substances in violation of 21 U.S.C. § 841(a)(1), and to maintain a drug-involved premises, in violation of 21 U.S.C. § 856(a)(2) (Count 1); illegal distribution of ketamine and esketamine, in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2 (Counts 3-14); and maintaining a drug-involved premises in violation of 21 U.S.C. § 856(a)(2) (Count 22). Defendants are also charged with conspiracy to commit health care fraud in violation of 18 U.S.C. § 1347(a)(1)

[1] Defendant Malik has also filed a Motion to Dismiss the Indictment (ECF No. 55) and a Motion to Compel Brady Material (ECF No. 53). Those motions will be addressed in a separate Report and Recommendation.

& (2) (Count 2) and seven counts of making false statements related to health care matters in violation of 18 U.S.C. §§ 1035 & 2 (Counts 15-21).

On February 28, 2024, within the time limits prescribed by the Court's Order Concerning Pretrial Motions, Dr. Malik filed three pretrial motions, including a Motion to Dismiss the Drug Trafficking Counts in the Indictment. ECF No. 54. The United States filed its response on March 28, 2024. ECF No. 64. Dr. Malik requested, and was granted, leave to file a Reply in support of the motion. ECF No. 74. At the defendant's request, on May 22, 2024, the Court held a hearing on the pending pretrial motions. Following the hearing, the Court ordered the preparation of a transcript to aid in the disposition of the pending pretrial motions. The hearing transcript was filed on June 12, 2024. ECF No. 85.

Based on the written submissions of the parties, the arguments made at the time of the pretrial motion hearing, and my review of the applicable law, for the reasons discussed below, I find that, even when the facts alleged in the indictment are taken as true, the indictment fails to state an offense against Dr. Malik.

DISCUSSION

Dr. Malik contends the drug trafficking counts in the indictment fail to state an offense against him and should be dismissed pursuant to Fed. R. Crim. P. 12(b)(3)(B)(v).[2] "An indictment is legally sufficient on its face if it contains all of the essential elements of the offense charged, fairly informs the defendant of the charges against which he must defend, and alleges sufficient information to allow a defendant to plead a conviction or acquittal as a bar to a subsequent prosecution." *United States v. Sholley-Gonzalez*, 996 F.3d 887, 893 (8th Cir. 2021) (cleaned up), *cert. denied*, 142 S. Ct. 817 (2022); *see also Hamling v. United States*, 418 U.S. 87, 117 (1974);

[2] Malik cites "Federal Rule 12(b)(6), *see* ECF No. 54, at p. 1, but the Court presumes this citation was in error and he intends to rely on Fed. R. Crim. P. 12(b)(3)(B)(v).

United States v. Leveke, 38 F.4th 662, 669 (8th Cir. 2022) (quoting *Sholley-Gonzalez*). Indictments are not reviewed "in a hyper technical fashion and should be 'deemed sufficient unless no reasonable construction can be said to charge the offense.'" *United States v. O'Hagan*, 139 F.3d 641, 651 (8th Cir. 1998) (quoting *United States v. Morris*, 18 F.3d 562, 568 (8th Cir. 1994)). "Furthermore, '[a]n indictment is normally sufficient if its language tracks the statutory language.'" *United States v. Hayes*, 574 F.3d 460, 472 (8th Cir. 2009) (quoting *United States v. Sewell*, 513 F.3d 820, 821 (8th Cir. 2008)).

An indictment is insufficient on its face if a substantive essential element is omitted. *United States v. Zangger*, 848 F.2d 923, 925 (8th Cir. 1988)."If an essential element of the charge has been omitted from the indictment, the omission is not cured by the bare citation of the charging statute." *Zangger*, 848 F.2d at 925; *see also O'Hagan*, 139 F.3d at 651 (quoting *Zangger*). In reviewing the sufficiency of an indictment, the government's allegations are accepted as true, without reference to allegations outside the indicting document. *United States v. Farm & Home Savings Association*, 932 F.2d 1256, 1259, n.3 (8th Cir. 1991).

Title 21 U.S.C. § 841(a)(1) of the Controlled Substances Act ("CSA") makes it a federal crime, "[e]xcept as authorized by this subchapter, . . . for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." Under Title 21 U.S.C. § 856(a)(2), "[e]xcept as authorized by this subchapter, . . . it shall be unlawful to . . . manage or control any place, . . . either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance." Counts 1, 3-14 and 22 of the Indictment charge Dr. Malik and his co-defendant, Dr. Ali, with violating Title 21

U.S.C. §§ 841(a)(1) and 856(a)(2) of the CSA by being in a drug trafficking conspiracy to (i) distribute and possess with intent to distribute ketamine and esketamine in violation of 21 U.S.C. § 841(a)(1) and to (ii) maintain a drug-involved premises for the purpose of unlawfully storing and distributing ketamine and esketamine in violation of 21 U.S.C. § 856(a)(2) (Count 1); distributing ketamine and esketamine in violation of 21 U.S.C. § 841(a)(1) (Counts 3-14); and maintaining a drug-involved premises in violation of 21 U.S.C. § 856(a)(2) (Count 22).

Based on the indictment and the parties' arguments at the hearing, the unauthorized/unlawful acts at issue involve Dr. Malik's COPE Ketamine Clinic. COPE was allegedly created by Malik in 2018 to provide ketamine infusions, which are administered intravenously, to treat serious mental health illnesses such as treatment-resistant depression, anxiety disorders, and post-traumatic stress disorder. *Id.* at ¶¶ 1 & 39. COPE and one or more of Malik's other health care related businesses operated in a commercial building located at 5000 Cedar Plaza Parkway in St. Louis (the "Cedar Plaza Building"). *See id.* at ¶ 9.

The indictment identifies unlawful/unauthorized acts that fall into two categories. The first category involves alleged distribution from an unregistered location. Specifically, the indictment alleges Dr. Malik managed or controlled a drug involved premises and conspired with Dr. Ali to maintain drug-involved premises in violation of § 856 because, although Dr. Malik's DEA Registration authorized him, at various times, to dispense controlled substances from Suites 300 and 350 of the Cedar Plaza Building, Dr. Malik's DEA registration never authorized him to dispense and/or store controlled substances in Suite 220 of the Cedar Plaza Building where COPE was located. *See id.* at ¶¶ 35-40 & 47.

The second category of alleged unlawful/unauthorized acts stem from Dr. Ali's unsupervised administration of ketamine and esketamine to patients of COPE, beginning in

December 2020. Specifically, the indictment alleges Dr. Malik was in a drug trafficking conspiracy and aided and abetted in unlawful distribution of ketamine and esketamine by Dr. Ali because, beginning in December 2020 during the COVID 19 pandemic, Dr. Malik allowed (and paid) Dr. Ali, who is not registered with the DEA, to administer ketamine infusions under his DEA registration without supervision and outside of Dr. Malik's physical presence. *See id.* at ¶¶ 41-46. The Indictment alleges Dr. Malik knew he was required to be physically present for infusions of ketamine and esketamine ordered under his DEA registration number. *Id.*

The indictment alleges that "[a]t all times relevant to this indictment, [Dr. Malik] was a psychiatrist, licensed to practice medicine in the state of Missouri" and Dr. Ali "was a medical doctor, licensed to practice medicine in the state of Missouri." *Id.* at ¶ 1-2. The indictment further asserts that "[k]etamine and esketamine (an isomer of ketamine) are schedule III controlled substances" and "[f]ederal law requires every person who dispenses controlled substances to obtain a [DEA] registration." *Id.* at ¶ 4. The term "'dispense' means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance." *Id.* "A separate [DEA] registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, or dispensed by a person." *Id.* at ¶ 7. "At all relevant times, Dr. Malik had two DEA registrations, which authorized him to dispense controlled substances in schedules II through V at the respective registered location." *Id.* at ¶ 8. Neither the indictment nor arguments made by the government suggest that either Dr. Malik or Dr. Ali dispensed or distributed ketamine and esketamine for non-medical purposes.

Dr. Malik argues that taking the foregoing allegations as true, the indictment fails to allege an offense against him. Specifically, he argues that, because the indictment acknowledges that he is a doctor who was authorized to dispense the controlled substances at issue, the government must plead and prove that the drugs were distributed with no legitimate medical purpose and that he subjectively knew the drugs were not distributed for a legitimate medical purpose. Dr. Malik contends the omission of those allegations renders the indictment fatally defective. In *United States v. Moore*, 423 U.S. 122 (1975), the Supreme Court examined the extent to which a doctor authorized by the DEA to dispense controlled substances can be prosecuted under § 841, the CSA's drug trafficking provision. The defendant in *Moore* was a doctor authorized to dispense methadone. *Id.* at 144. He challenged his conviction under § 841, and the D.C. Circuit Court of Appeals reversed, holding that registrants could not be prosecuted under § 841 under any circumstances. *Id.* at 127-28. The court of appeals also held that Congress intended to subject registered physicians to prosecution only under §§ 842-843 of the CSA, which prescribe less severe penalties than § 841. *Id.* at 128-29.

The Supreme Court reversed the D.C. Circuit Court of Appeals, rejecting the argument that Congress intended to exempt doctors from prosecution under § 841 by virtue of their status as registrants alone. *Id.* at 131. The Court also rejected the argument that Congress intended to establish two mutually exclusive penalty systems for registrants and non-registrants. *Id.* at 133-34. The Court held, instead, that the defendant could be criminally liable under § 841 because there was evidence that he was acting as a "large-scale 'pusher' and not as a physician." *Id.* at 142-43. Relying primarily on the Harrison Act and the CSA's legislative history, the Court reasoned that whether a registrant should or should not be criminally liable under § 841 turns on whether the registered doctor used his or her authority to dispense controlled substances "not for legitimate

purposes, but primarily for the profits to be derived therefrom." *Id.* at 135 (quoting H.R. Rep. No. 91-444, p. 10). The Court noted that "the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.'" *Id.* at 140. Thus, "[i]mplicit in the registration of a physician is the understanding that he is authorized only to act 'as a physician.'" *Id.* at 141. On the facts before it, the Court held that the evidence presented at trial was sufficient for the jury to find that the doctor's conduct "exceeded the bounds of professional practice" and thus that he could be held criminally liable under section 841. *Id.* at 142 (internal quotation marks omitted).

Following the decision in *Moore*, circuit courts, including the Eighth Circuit, have consistently held that when the government prosecutes registered doctors (or other practitioners) under § 841, the government must prove, beyond a reasonable doubt, that the doctor or practitioner acted outside the usual course of their professional practice. *See United States v. Elder*, 682 F.3d 1065, 1068-69 (8th Cir. 2012) ("When the alleged offense involves the distribution of drugs prescribed by a licensed physician registered under the federal Controlled Substances Act, the government must prove that the physician's activities 'fall outside the usual course of professional practice.'") (quoting *Moore*, 423 U.S. at 124); *United States v. Kanner*, 603 F.3d 530, 532-35 (8th Cir. 2010) (drug trafficking count pursuant to § 841 not subject to dismissal because indictment charged "that physicians and pharmacists contracted by [defendant's company] acted in a manner inconsistent with the usual course of professional practice in violation of the rule established in *Moore*"); *United States v. Katz*, 445 F.3d 1023, 1028 (8th Cir. 2006) (holding prosecution of a registered doctor requires "proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance

of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e., the personal profit of the physician") (quoting *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994)); *United States v. Seelig,* 622 F.2d 207, 212-13 (6th Cir. 1980) ("Implicit in *Moore* is that registered doctors (or other practitioners) are exempt from criminal liability under § 841(a)(1) unless they were acting outside the usual course of professional practice.").

A. THE LEGITIMATE MEDICAL PURPOSE EXCEPTION FROM *MOORE* APPLIES.

The government argues it is not required to prove Dr. Malik acted with no legitimate medical purpose or that he acted outside the bounds of professional medical practice. It argues the theory of criminal liability presented to the grand jury, and with which Dr. Malik is charged, is that he conspired with an unregistered doctor—Dr. Ali—to illegally ***administer*** controlled substances to patients at times when Dr. Malik was not physically present. *Id.* The government posits it is not required to satisfy the "no legitimate medical purpose" requirement because that requirement applies only in cases where the registered doctor is charged with illegally ***prescribing*** controlled substances. *Id.* at p. 8-12. This Court disagrees.

As noted above, the Court in *Moore* analyzed the CSA "against the background of the legislative history" and concluded that Congress intended "to limit a registered physician's ***dispensing*** authority to the course of his 'professional practice.'" *Moore*, 423 U.S. at 140 (emphasis added). As the government acknowledges, under the CSA, the term "dispense" includes both administering and prescribing of controlled substances. ECF No. 69, at p. 8 ("The term 'dispense' means 'to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance. . . . .'") (quoting 21 U.S.C. § 802(10)). Nothing about the Court's reasoning in *Moore*

suggests that its central holding turned on whether a physician was dispensing a controlled substance by prescription versus dispensing a controlled substance by administering directly to the body of a patient. Instead, citing the Harrison Act and other legislative history, the Court in *Moore* focused more generally on the "nature of the drug transaction" and concluded that when a drug transaction by a registered doctor exceeds the bounds of the doctor's professional practice and lacks a legitimate medical purpose, the doctor is acting "except as authorized" and can be convicted under the drug trafficking provisions of the CSA. *See id.* at 134-35 ("the penalty to be imposed for a violation was intended to turn on whether the 'transaction' falls within or without legitimate channels . . . [and] severe criminal penalties were imposed on those, like respondent, who sold drugs, not for legitimate purposes, but primarily for the profits to be derived therefrom."). *See also United States v. Henson,* Case No. 16-10018-JWB, 2024 WL 81201, at *1 (D. Kan., Jan. 5, 2024) (interpreting *Moore,* the court held, "[T]he Supreme Court engrafted a standard into the act based on the Harrison Act. Thus, registrants are subject to prosecution under § 841 when operating outside the usual course of professional practice.") (internal citation omitted).[3]

[3] Unlike the regulation governing prescribing of controlled substances, *see* 21 C.F.R. § 1306.04(a), the regulations governing the administering of controlled substances do not explicitly require that the drugs be administered for a legitimate medical purpose. *See* 21 C.F.R. § 1301.22(b); 19 C.S.R. §§ 30-1.066(1)(A). Taken to its logical conclusion, the government's argument that the scope of Dr. Malik's authorization to dispense controlled substances is defined solely by governing regulations and not by the "legitimate channels" standard articulated in *Moore* would lead to the bizarre conclusion that Dr. Malik could, without violating § 841, inject patients with the controlled substances at issue for no legitimate medical reason so long as Dr. Malik himself injected patients with the controlled substances or directed Dr. Ali to do so while he was physically present. When it rejected the argument that registered doctors could only be prosecuted under §§ 842 and 843 of the CSA, the Court in *Moore* addressed a similar dissonance that could result from an overly narrow interpretation of the CSA. The Court held, "if violation of § 829 [regarding the issuing of prescriptions] were the sole basis for prosecution," a "physician who wished to traffic in drugs without threat of criminal prosecution could . . . simply dispense drugs directly without the formality of issuing a prescription. Direct dispensing is exempt from § 829 and thus is not reached by any subsection of § 842 or § 843 so long as the technical requirements are complied with." *Moore*, 423 U.S. at 137.

Although most cases applying *Moore*'s legitimate medical purpose exception arise in the context of a doctor's authority to ***prescribe*** controlled substances, this Court has found at least one circuit court decision in which the legitimate medical purpose requirement was applied in a case involving one of the alleged unauthorized acts in this case—dispensing controlled substances from an unregistered location. In *United States v. Goldstein,* 695 F.2d 1228, 1231-33 (10th Cir. 1981), a registered doctor and two pharmacists were convicted under § 841 for dispensing drugs from an unregistered pharmacy. On appeal, the Tenth Circuit reversed the drug trafficking convictions, noting that "the Government made no allegation in the indictment and presented no evidence at trial that the prescriptions written by [the doctor] and filled by [the pharmacists] were not prescribed for legitimate medical purposes in the usual course of professional treatment. *Id.* at 1231. The government argued that the legitimate medical purpose rule from *Moore* did not apply because *Moore* and similar cases did not involve dispensing drugs from an unregistered pharmacy. *See id.* at 1232. The Tenth Circuit rejected that argument, holding:

> This distinction is not persuasive in view of the significant observations made by the Supreme Court in [*Moore*]. There the Court held that registered physicians can be prosecuted under section 841 when their activities fall outside the usual course of professional practice . . . . [I]n so holding, the Court emphasized that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant.' . . . The Court also pointed out that the penalty to be imposed for a violation was intended to turn on whether the 'transaction' falls within or without legitimate channels. All persons who engage in legitimate transactions must be registered and are subject to penalties under §§ 842 and 843 for '[m]ore or less technical violations.' But 'severe criminal penalties' were imposed on those, like respondent, who sold drugs, not for legitimate purposes, but 'primarily for the profits to be derived therefrom.

Id. at 1232-33 (internal citations omitted).

The court in *Goldstein* noted that "[n]umerous decisions of this and other circuits have held that a physician or pharmacist who is registered and who dispenses controlled substances in the usual course of professional conduct is immune from prosecution under [§]841(a)(1))." *Id.* at 1233.

The court concluded the reasoning from *Moore* was "a clear indication that only those drug transactions occurring outside legitimate distribution channels may be prosecuted under section 841(a)(1)." *Id.* *See also United States v. Seelig,* 622 F.2d 207, 212-13 (6th Cir. 1980) ("Implicit in *Moore* is that registered doctors (or other practitioners) are exempt from criminal liability under § 841(a)(1) unless they were acting outside the usual course of professional practice").

The government's reliance on cases such as *United States v. Blanton*, 730 F.2d 1425, 1427 (11th Cir. 1984), *United States v. Cheek,* 592 F. App'x. 179, 181-82 (6th Cir. 2014), and *United States v. Jones*, 816 F.2d 1483, 1484 (10th Cir. 1987), is misplaced with respect to Dr. Malik. In *Blanton*, the legitimate medical purpose rule from *Moore* did not apply because, unlike Dr. Malik, the physician-defendant in *Blanton* had a DEA registration that did not permit him to dispense the drugs at issue in the case. *Blanton,* 730 F.2d at 1430 (rejecting the doctor's reliance on *Moore* and explaining that "*Moore* involved the question of whether a physician could ever be prosecuted under section 841(a)(1) for dispensing drugs *for which he was registered*") (emphasis in original). Similarly, the physician-defendant in *Cheek* had previously been registered but had her DEA registration revoked. 592 F. App'x. at 181-82. As such, her transactions were considered unauthorized and not subject to the exception articulated in *Moore* and its progeny. Finally, in *Jones,* a physician's assistant who was not registered by the DEA and who, it turns out, was not authorized by the doctor he worked for to dispense under the doctor's DEA registration, was convicted under § 841. 816 F.2d 1484-85. Citing the Tenth Circuit's decision in *Goldstein,* the physician's assistant argued that "even if the prescriptions were not authorized by [the supervising doctor] his conviction cannot be sustained if he prescribed controlled substances for valid medical reasons." *Id.* at 1485. The Tenth Circuit rejected that argument, holding *Goldstein* (and by implication *Moore*) did not apply because "[a]lthough some of [defendant's] prescriptions may

have been for valid medical reasons, defendant is not a physician nor is he registered with the DEA." *Id.*

The facts in *Blanton, Cheek* and *Jones* stand in sharp contrast to the facts of this case. The indictment in this case admits that Dr. Malik was a physician authorized to dispense the controlled substances at issue at all relevant times. ECF No. 2, ¶¶ 1 & 8. On its face, the indictment alleges Dr. Malik ***is*** a physician who is not only registered with the DEA, but authorized to dispense the controlled substances at issue. *Id.* Thus, the facts of this case are less like *Blanton, Cheek* and *Jones* and more like *Goldstein,* in which the Tenth Circuit held that "only those drug transactions occurring outside legitimate distribution channels may be prosecuted under section 841(a)(1)." *Goldstein,* 695 F.2d at 1233.

B. THE INDICTMENT FAILS TO STATE AN OFFENSE AGAINST DR. MALIK.

Although the indictment in this case sets out alleged "unauthorized" acts, it does not allege that Dr. Malik distributed or dispensed ketamine or esketamine for no legitimate medical purpose or outside the bounds of his professional medical practice. Following *Moore,* circuits were split over whether the legitimate medical purpose/professional practice exception is an essential element that must be alleged in an indictment against a registered doctor. *See United States v. Steele,* 147 F.3d 1316, 1320 (11th Cir. 1998) ("[A]n indictment charging a practitioner with violating 21 U.S.C. § 841(a)(1) need not negative the course of professional practice exception . . . ."); *United States v. Polan,* 970 F.2d 1280, 1282 (3d Cir. 1992) (indictment of physician for distributing and conspiring to distribute controlled substance not defective for failure to allege absence of legitimate medical reason); *United States v. Roya,* 574 F.2d 386, 391 (7th Cir. 1978) (rejecting a physician defendant's argument that an indictment charging him with violations of sections 841(a)(1) and 846 should have been dismissed because it failed to allege that the

dispensing was "without a legitimate medical purpose."). *But see United States v. Outler,* 659 F.2d 1306, 1309 (5th Cir. Unit B 1981) (holding "the lack of a legitimate medical reason is an essential element of [the offense of violating 21 U.S.C. § 841(a), and therefore must be alleged in the indictment"; noting that the element "embodies the culpability of the offense" because "[w]ithout behavior beyond professional practice, there is no crime"), overruled by *United States v. Steele,* 147 F.3d 1316, 1320 (11th Cir. 1999) (en banc);[4] *United States v. King,* 587 F.2d 956, 962-65 (9th Cir. 1978) (holding that a controlled substance offense indictment against a medical practitioner must allege the physician acted without authorization).

Courts that previously held the legitimate medical purpose/course of professional practice exception is not an essential element that must be alleged in an indictment did so in reliance on § 885(a)(1) of the CSA, which provides that "[i]t shall not be necessary for the United States to negative any exemption or exception set forth in [21 U.S.C. §§ 801–904] in any complaint, information, indictment, or other pleading . . . and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit." 21 U.S.C. § 885(a)(1). In other words, these courts interpreted § 885(a)(1) to mean that an exception like the legitimate medical purpose/course of professional practice exception is an affirmative defense that need not be alleged in the indictment. *See, e.g., Steele,* 147 F.3d at 1320 (holding that through § 885(a)(1), Congress clearly and definitively "exercised its right to say . . . [that] all exceptions to the prohibition against manufacturing, distributing, dispensing, and possessing controlled substances, are defenses not elements, and that their inapplicability need not be alleged in the indictment").

[4] *Outler* was decided by Unit B of the former Fifth Circuit during the transitional period that occurred while dividing the former Fifth Circuit into the new Fifth Circuit and the Eleventh Circuit. The Eleventh Circuit has since overruled *Outler*, *see Steele,* 147 F.3d 1316, but *Outler* appears to still be binding precedent in the Fifth Circuit.

The Supreme Court recently called that interpretation of § 885 into question in *Ruan v. United States,* 597 U.S. 450 (2022). In *Ruan,* the Supreme Court examined what "state of mind" the government must prove to convict registered doctors of violating § 841. *Id.* at 454. Defendants in *Ruan* were medical doctors licensed to prescribe controlled substances. *Id.* at 455. Each doctor was tried and convicted for violating § 841 for prescribing controlled substances in an unauthorized manner. *Id*. One defendant, Ruan, challenged the district court's rejection of jury instructions that would have required the jury to find that he subjectively knew his prescriptions fell outside the scope of the standard medical practice. *Id.* at 455-56. The Eleventh Circuit affirmed his convictions, holding that whether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard. *Id.* at 456. The other defendant, Kahn, challenged the *mens rea* required by his own jury instructions. *Id.* The Tenth Circuit affirmed his convictions, holding that a conviction requires the jury to find that a doctor either subjectively knew a prescription was issued not for a legitimate medical purpose or issued a prescription that was objectively not in the usual course of professional practice. *Id.* at 456-57. The Supreme Court granted Ruan's and Kahn's separate petitions for certiorari and consolidated the cases to consider what *mens rea* applies to the authorization exception to § 841. *Id.* at 457.

In urging the Court to affirm the convictions, the government argued that the "except as authorized" clause differs from a traditional element because, under § 885, the government does not need to anticipate or foreclose affirmative defenses. *Id.* at 462. The Court's majority pushed back on that interpretation of § 885. It noted that Section 885 has two purposes. First, Section 885 "absolves the Government of having to allege, in an indictment, the inapplicability of every statutory exception in each Controlled Substances Act prosecution." *Id.* at 463. Second, by

shifting, first, the burden of production of evidence of authorization to the defendant, then shifting the burden of persuasion that the defendant lacked authorization back to the government, Section 885 "relieves the Government from having to disprove, at the outset of every Controlled Substances Act prosecution every exception in the statutory scheme." *Id.* at 464.The Court held that "even assuming that lack of authorization is unlike an element" for the purposes of § 885, lack of authorization "is sufficiently like an element in respect to [scienter requirements] as to warrant similar treatment." *Id.* at 464. The Supreme Court ultimately reversed the convictions of Ruan and Kahn, holding the lower courts applied the wrong *mens rea* standard. The Court held:

> [T]he statute's "knowingly or intentionally" *mens rea* applies to authorization. After a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.

Id. at 454.

Following *Ruan*, at least one court has rejected the argument that, under all circumstances, § 885 absolves the government of needing to plead lack of a legitimate medical purpose in the indictment:

> [W]here the government chose to charge [d]efendant as a doctor registered to dispense controlled substances under the Controlled Substances Act, the government must allege lack of authorization and knowledge thereof to sufficiently state the elements of the offense. In other words, although § 885 states that the government is not *required* to negate exceptions in the indictment that might preclude conviction under § 841, when the government elects to address such an exception in the indictment, it is required to do so in a manner that states an offense.

Henson, 2024 WL 81201, at *2-*3 (emphasis in original) (rejecting the government's argument that under § 885 it need not allege lack of authorization in the indictment, but finding the indictment sufficient to state an offense where it alleged that the defendant "did knowingly and intentionally distribute, dispense, and possess with the intent to distribute prescription drugs . . .

outside the usual course of professional medical practice and without a legitimate medical purpose."). *See also United States v. Purpera*, Case Nos. 20-4543, 20-4544, 2024 WL 2764715, at *1 (4th Cir. May 30, 2024) (holding *Ruan* "add[ed] a scienter element for illegal drug distributions under § 841 by medical professionals.").

This Court finds the *Henson* court's interpretation of *Ruan* persuasive and consistent with the law in the Eighth Circuit. Although the undersigned has found no Eighth Circuit decision that squarely addressed the question of whether an indictment that fails to allege lack of legitimate medical purpose is defective when the defendant is a registered doctor, pre-*Ruan* cases suggest the Eighth Circuit has always treated the legitimate medical purpose/course of medical practice exception like an element in § 841 prosecutions against registered doctors. *See, e.g., Kanner*, 603 F.3d at 532-35 (holding drug trafficking count pursuant to § 841 not subject to dismissal because indictment charged "that physicians and pharmacists contracted by [defendant's company] acted in a manner inconsistent with the usual course of professional practice in violation of the rule established in *Moore*"); *Katz*, 445 F.3d at 1028 (holding prosecution of a registered doctor requires "proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice").

Applying the reasoning from *Moore, Ruan,* and *Henson* to the facts of this case, the indictment admits Dr. Malik was registered and authorized to dispense ketamine and esketamine at all relevant times. As such, having conceded at the outset that Dr. Malik was registered and authorized to dispense ketamine and esketamine, the government was required to "allege lack of authorization and knowledge thereof to sufficiently state the elements of the offense." *Henson*, 2024 WL 81201 at *2. Under *Moore*, a registered doctor is exposed to criminal liability for drug trafficking only when that doctor engages in drug transactions that exceed the bounds of a

registered doctor's professional practice and that lack a legitimate medical purpose. *See Moore,* 423 U.S. at 134-35 ("the penalty to be imposed for a violation was intended to turn on whether the 'transaction' falls within or without legitimate channels . . . [and] severe criminal penalties were imposed on those, like respondent, who sold drugs, not for legitimate purposes, but primarily for the profits to be derived therefrom."); *United States v. Katz*, 445 F.3d 1023, 1028 (8th Cir. 2006) (holding prosecution of a registered doctor requires "proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e., the personal profit of the physician") (quoting *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994)); *United States v. Seelig,* 622 F.2d 207, 212-13 (6th Cir. 1980) ("Implicit in *Moore* is that registered doctors (or other practitioners) are exempt from criminal liability under § 841(a)(1) unless they were acting outside the usual course of professional practice."). As such, the indictment is defective because it fails to allege that Dr. Malik knowingly acted with no legitimate medical purpose and outside the bounds of his professional medical practice.[5]

[5] The indictment admittedly describes allegedly unauthorized acts knowingly committed by Dr. Malik, such as dispensing from an unregistered location and permitting an unregistered doctor to dispense to patients when Dr. Malik was not physically present. However, these allegations are not sufficient to state a drug trafficking offense against Dr. Malik. Under *Moore*, drug transactions that exceed the bounds of a registered doctor's professional practice and that lack a legitimate medical purpose, cross the line that separates authorized conduct from unauthorized and unlawful conduct under the CSA. *See Moore,* 423 U.S. at 134-35. The unauthorized acts alleged appear to be "more or less technical violations" and are not enough to put Dr. Malik on notice that the government is prosecuting him for conduct that, under *Moore*, crossed the line from legitimate distribution of controlled substances to illegitimate distribution of controlled substances. *See Goldstein*, 695 F.2d at 1233 (holding the reasoning in *Moore* clearly indicated "that only those drug transactions occurring outside legitimate distribution channels may be prosecuted under section 841(a)(1)").

In its brief and at oral argument the government made clear that the lack of legitimate medical purpose and usual course of professional medical practice was not the theory of criminal liability presented to the grand jury. Because the government has clearly signaled that the grand jury was not required to find that Dr. Malik acted with no legitimate medical purpose and outside the bounds of his professional medical practice, the Court further finds dismissal of the indictment is necessary to protect Dr. Malik's Fifth Amendment right to be tried on charges found by a grand jury. *See Zangger*, 848 F.2d at 925 ("Because the statutory citation [appearing in Zangger's indictment] does not ensure the grand jury has considered and found all essential elements of the offense charged, the indictment violates Zangger's fifth amendment right to be tried on charges found by a grand jury.") (internal citations and quotation marks omitted).

Accordingly,

IT IS HEREBY RECOMMENDED, that Defendant's Motion to Dismiss the Drug Trafficking Counts in the Indictment (ECF No. 54) be **GRANTED**.

The parties are advised that they have fourteen (14) days in which to file written objections to this recommendation and determination. Failure to timely file objections may result in waiver of the right to appeal questions of fact. *Thompson v. Nix,* 897 F.2d 356, 357 (8th Cir. 1990).

Trial in this case will be set before the Honorable Henry E. Autrey, by separate order.

SHIRLEY PADMORE MENSAH
UNITED STATES MAGISTRATE JUDGE

Dated: August 5, 2024